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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------|-------------|----------------------|---------------------|------------------|
| 10/698,496 | 10/31/2003 | Steven L. Jacques | 19799-206 | 9597 |
| 21890 | 7590 | 05/30/2007 | EXAMINER | |
| PROSKAUER ROSE LLP | | | NGUYEN, TUAN VAN | |
| PATENT DEPARTMENT | | | | |
| 1585 BROADWAY | | | ART UNIT | PAPER NUMBER |
| NEW YORK, NY 10036-8299 | | | 3731 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|----------------------------|------|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/698,496 | JACQUES, STEVEN L. | |
| | Examiner | Art Unit Tuan V. Nguyen | 3731 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 March 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-29 is/are pending in the application.
 - 4a) Of the above claim(s) 1-13 and 25 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 14-29 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 October 2004 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAIL ACTION

Response to Amendment

1. According to the Amendment applicant filed on March 09, 2007, applicant added claim 26-29. Now claims 1-29 are pending in this present application.
2. Applicant amended to claim 15 to overcome the objection, therefore, the objection to claim 15 in previous Office Action is hereby withdrawn.
3. Applicant argument with respect to claim 14 has been fully considered and persuasive, therefore, the rejection is hereby withdrawn.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 14, 15, 19-24 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins et al. (U.S. 6,676,659) in view of Richardson (U.S. Pub. No. 2003/0078473) further in view of Boston Scientific (Autotome RX Cannulating Sphincterotomes product brochure; 510(k) Summay issued by FDA and posted to the public on October 21, 2001; and 2001, Produc For Endoscopy, Price List and Ordering Information).**
7. Referring to claims 14, 15, 23-24 and 26-28, Hutchins discloses (see Figs. 3, 4, and 6) a papillotomy and sphincterotomy device comprising: a shaft 11 having proximal end and distal end; a distal terminus 14, one lumen for receiving 0.35 inches guide wire; one lumen 17 for cutting wire 37; wherein the cutting wire 37 is exiting a skive hole 36B then entering the second skive hole 36A and the distal tip of cutting wire is anchor by anchoring member 35; the thirds lumen 16; and the distal tip wherein the distal tip having a diameter measuring 0.07 and the distal tapered tip (see col. 5, line 45 to col. 7, line 14). Hutchins discloses the invention substantially as claimed except for the specific length of the taper tip of approximately 3 mm or less and the tip diameter less than approximately 0.063 inch.
8. Still referring to **claims 14, 15, 23-24 and 26-28**, however, Richardson discloses a billary catheter (see Fig. 3) having a tapered distal tip wherein the length of the tapered tip is about 0.10 to 5.0 cm or 1 millimeter to 50 millimeters for the purpose

increase the probability of initially getting into a smaller opening such as the orifice of Vater (see paragraph [0038]-[0039]). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to use the tapered tip design, as disclosed by Richardson, to incorporate into the device, as disclosed by Hutchins because this will provide the advantage aforementioned above as suggested by Richardson.

9. Still referring to **claims 14, 15, 23-24 and 26-28**, further, Boston Scientific (see Autotome Rx Cannulating Sphincterotomes product brochure and 510(k) Summary, which issued by the FDA, posted to the public on October 21, 2001) discloses a sphincterotome having the tip outer diameter of 4.9 Fr or 0.064 inches. The 510(k) Summary, which issued by the FDA, published on October 21, 2001, indicates that Boston Scientific intent to market the device. Therefore, it would have been obvious to one of ordinary skill in the art to incorporate a sphincterotome having a tip outer diameter as suggested by Boston Scientific into the modified device of Hutchins to provide the surgeon a product that having different size of tip diameter to facilitate ease of entering the biliary ducts in a common bile duct thereby greatly reduce patient trauma and the length of a hospital stay and recovery times. Further, Boston Scientific discloses (see 2001, Product For Endoscopy, Price List and Ordering Information) a sphincterotome having a tip outer diameter of 3.5 Fr or 0.046 inches.
10. Referring to **claim 23-24 and 26**, it would have been obvious to one having ordinary skill in the art to design a catheter having an outside diameter of

approximately 0.055 inch to 0.063 inch, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

11. Referring to **claims 20 and 21**, here it is noted that a comparison of the recited process with the prior art processes does NOT serve to resolve the issue concerning patentability of the product. In re Fessman, 489 F2d 742, 180 U.S.P.Q. 324 (CCPA 1974). Whether a product is patentable depends on whether it is known in the art or it is obvious, and is not governed by whether the process by which it is made is patentable. In re Klug, 333 F2d 905, 142 U.S.P.Q 161 (CCPA 1964). In an ex parte case, product-by-process claims are not construed as being limited to the product formed by the specific process recited. In re Hirao et al., 535 F2d 67, 190 U.S.P.Q. 15, see footnote 3.
12. Referring to **claim 29**, Hutchins discloses (see Fig. 6) the distal end portion, which includes wire 37 and the distal tip, has a length of 6 cm to 9 cm or 60 millimeters to 90 millimeter. Therefore, it would have been obvious to one of ordinary skill in the art to modified the distal tip, which from 36A to the distal end of the tip portion, having a taper and having a length of 4.5 mm to 6 mm as suggested by Richardson because it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

13. **Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchins et al. in view of Richardson further in view of Boston Scientific and further in view of Sadamasa (U.S. 6,017,339).**
14. Referring to claims 17 and 18, the modified device of Richardson discloses the invention substantially as claimed except for the radiopaque marker located at the distal end of the cutting wire and inside the lumen of the cutting wire. Sadamasa discloses an endoscopic diathermic knife (see Fig. 2) for performing endoscopic papillotomy or sphincterotomy (see Background of The Invention) having a radiopaque marker 21 at the distal of the cutting wire 16a and inside the lumen of the cutting wire for the purpose of locating the location of the distal tip (see col. 6, lines 18-32). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the marker to the cutting wire, as disclosed by Sadamasa, to incorporate into the modified device, as disclosed by Hutchins because this will provide the advantage aforementioned above as suggested by Sadamasa.

Conclusion

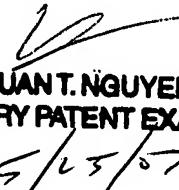
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
May 21, 2007


ANHTUANT. NGUYEN
SUPERVISORY PATENT EXAMINER

5/23/07